Comparing Fascia Iliaca Compartment Block with Pericapsular Nerve Group Block for Hip Fracture Pain Control before Operation

Study Protocol with SAP (statistical analysis plan)

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Background

Hip fracture is a global health care concern. It is estimated that the number of hip fractures globally was 1.6 million in 2000[1], and will be increased to 6.25 million by 2050[2]. Timely surgery is the mainstay of treatment for hip fractures[3]. Before operation, pain management for hip fracture is a clinical challenge. The fracture-induced pain is so intense that medical treatment with acetaminophen, non-steroid anti-inflammatory drugs (NSAIDs) or opioids may not provide adequate analgesia. Furthermore, opioid analgesia is limited by side effects such as nausea, vomiting, dizziness, sedation, and respiratory depression. On the contrary, peripheral nerve block provides better pain control for hip fracture than opioids [4,5]. Fascia iliaca compartment block (FIC block), for example, has been repeatedly shown to be superior to opioids for pain control for hip fracture[5,6]. Recently, a novel peripheral nerve block technique, the "pericapsular nerve group block (PENG block)[7]", has been developed for hip fracture pain control. PENG block is considered to provide better coverage of articular branches from the obturator nerve than FIC block, and thus might be superior to FIC block in hip fracture pain control. However, there is no study comparing the analgesic effect for hip fracture pain between the FIC block and PENG block.

Aim

The aim of this study is to compare the analgesic effect of FIC block and PENG block in hip fracture pain control.

Methods

This will be a randomized, assessor and participant-blinded study. Adult patients (aged 20 years or older) scheduled for surgical treatment for hip fracture with American Society of Anesthesiologists (ASA) physical status I-III will be assessed for eligibility to participate the study. The exclusion criteria includes: allergy to local anesthetics, pregnancy, inability to understand and use the numerical rating scale (NRS 0-10, 0: no pain, 10: worst pain imaginable) after instruction, chronic use of opioids, coagulopathy, neuropathy or severe diabetic mellitus. If the patients give his /her informed consents, his/her baseline demographic data (gender, age, height, and body weight) and types of hip fracture will be recorded. Participants will be randomly allocated into either FIC block or PENG block by using the website RESEARCH RANDOMIZER (https://www.randomizer.org). One of the two anesthesiologists experienced in performed the FIC and PENG blocks will perform the nerve blocks. Only the anesthesiologist performing the nerve block and his assistant will be aware of which nerve block the participant received immediately

before performing nerve block by opening a sealed envelope. The assessors, in-charge anesthesiologists and nurse anesthetists, operation room personnel, surgeons and study participants will be all blinded to the randomization. The participants are unlikely to know which nerve block they receive because the needle insertion sites and needle trajectories of these two nerve blocks are quite close to each other.

On arrival of the operating theater, all participants will be sent to the nerve block area, where continuous electrocardiogram (ECG), pulse oximetry, and non-invasive intermittent blood pressure monitoring will be applied and an intravenous line will be established. Before any intervention, pain at rest and during the fractured lower limb being passively internal rotated in extension to neutral position from its usual externally rotated deformity by assessors will assessed using NRS. If the participant cannot tolerate passive internal rotation of his/her fractured limb due to pain, impossibility to perform the test will be recorded as well as the worst NRS score during these attempts. The same assessment will be performed every 10 mins for until 30 mins after completion of the nerve block. Then the patient will be sent to the operation room, where spinal anesthesia will be performed for the surgery.

Procedures of the nerve blocks

A supra-inguinal FIC block will be performed in the way as described previously[8, 9]. A linear ultrasound transducer (6-15 MHz, SonoSite, M-Turbo, USA) is placed in a sagittal plane to identify the anterior superior iliac spine (ASIS). By sliding the transducer medially, the fascia iliaca and abdominal internal oblique, satorius, and iliopsoas muscles are identified. After identifying the “bow-tie sign”, a 23-gauge needle (7mm, Nipro, Japan) is inserted in plane from caudal to cephalad until the needle tip penetrate the fascia iliaca. After negative aspiration, 0.35% ropivacaine 30mL with 1:400,000 epinephrine will be injected to separate the fascia iliaca and the iliacus muscle.

The PENG block will be performed as previously described[7]. A curvilinear ultrasound transducer (2-5 MHz, SonoSite, M-Turbo, USA) is initially place on the anterior inferior iliac spine (AIIS) and then aligned to the iliopubic eminence by rotating around 45 degree. In this view, the iliopubic eminence, iliapsoas muscle and tendon, pectineus muscle, femoral artery and vein will be identified. A 23-gauge needle (7mm, Nipro, Japan) is inserted in plane from lateral to medial until the needle tip in the musculofascial plane between the psoas tendon anteriorly and the pubic ramus posteriorly. After negative aspiration, 0.35% ropivacaine 20mL with 1:400,000 epinephrine will be injected.

Outcome measurements

The primary outcome of this study is the pain measurement at rest and during the fractured limb being passively internally rotated 30 mins after nerve block. The secondary outcomes includes the pain measurement during positioning for spinal anesthesia (from supine to lateral decubitus with flexion of the healthy hip), pain measurement at 6, 12, and 24 hours after operation, the time spending for performing spinal anesthesia (defined as starting of positioning maneuver to removal of spinal needle), quality of position for spinal anesthesia (characterized as unsatisfied, satisfied, good, and excellent by the anesthesiologists performing the spinal anesthesia), the time interval between the end of operation and pain first perceived by the patient, the time interval between the end of operation and the first request for rescue analgesics, total consumption of rescue analgesics within 24 hours after the operation, the time interval between the end of operation and the first time the patient can ambulate with assistance after operation, the time spending for nerve block (defined as from contact of skin by the ultrasound transducer to removal of the needle), and satisfaction of the patient regarding preoperative analgesia from nerve block (very good, good, adequate, poor, very poor) inquired on the 1st postoperative day.

Statistics

Based on a previous study, the standard deviation of pain score after FIC block was 2.4[10]. Assuming the minimal clinically important difference in NRS score is 1.5, 44 patients in each group are required to achieve a power of 80% and a level of significance of 5% (two sided). One hundred eligible patients (50 patients in each group) will be enrolled in the study after informed consents are obtained. The data of normal distribution will be analyzed with independent *t*-test, otherwise Mann-Whiteny U test will be used for analyses. Categorical data will be analyzed using χ^2 test or Fisher's exact test. $P < 0.05$ will be considered statistically significant.

There is no conflict of interest.

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